



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

The Honorable Ron Wyden
United States Senate
Washington, D.C. 20510-3703

MAY 12 1999

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Dear Senator Wyden:

Thank you for your letter of April 15, 1999, co-signed by Senator Gordon H. Smith, on behalf of the West Coast shellfish industry, concerning the petition for a performance standard for *Vibrio vulnificus* in shellfish filed with the Food and Drug Administration (FDA or the Agency) by the Center for Science in the Public Interest. FDA published a request for comments on this petition in the Federal Register of January 21, 1999.

You express concern that the Interstate Shellfish Sanitation Conference (ISSC) may have been circumvented by the petition process and recommend that any further action on this issue involve the ISSC. You give as an example the recent work of the ISSC with the West Coast shellfish industry in development of a control plan for *Vibrio parahaemolyticus*.

Thank you for your thoughtful comments. We have entered them into the Administrative Record for this petition and they will be considered in the Agency's deliberations on this petition.

Please contact us if we may be of further assistance in this matter. A similar letter has been sent to Senator Smith.

Sincerely,

Melinda Plaisier
Interim Associate Commissioner
for Legislative Affairs

cc: HFA-305 (Docket No 98P-0504)

98P-0504

ANS5

United States Senate

WASHINGTON, DC 20510

April 15, 1999

Jane E. Henney, Commissioner
U. S. Food and Drug Administration
5600 Fisher's Lane
Rockville, MD 20857

Dear Commissioner Henney:

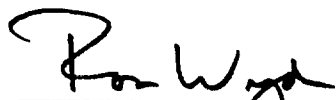
We are writing in response to the Food and Drug Administration (FDA) Request for Comments [Docket No. 98P-0504] on performance standards for *Vibrio vulnificus* and *Vibrio parahaemolyticus*. We are concerned the Interstate Shellfish Sanitation Conference (ISSC), which normally plays an important role in establishing policies and regulations for shellfish safety, may have been circumvented. In addition, we question the advisability of basing public health policy on the last two anomalous hot (El Nino) summers, and we recommend any further action in response to the Request for Comments involve the ISSC.

Since 1982, the Interstate Shellfish Sanitation Conference has brought state and federal regulatory agencies, the shellfish industry and the academic community together to promote enhanced shellfish safety. Although the West Coast shellfish industry has experienced some frustration with the ISSC process in the past, especially with respect to the Gulf Coast's historical problems with *V. vulnificus*, it is our understanding the industry still believes the ISSC process is the democratic solution to many complex issues related to shellfish safety.

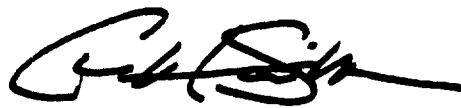
On the West Coast, where *V. parahaemolyticus* has been a problem, particularly for the past two uncommonly warm summers, the shellfish industry worked with their regulators through the ISSC process to develop a control plan. That plan, put into place this past summer, appears to have been highly effective in reducing illnesses caused by these bacteria. Since the plan also calls for data collection while simultaneously reducing illnesses, it would appear to be a logical course of action to continue using the plan through the next two summers to better assess the situation. These are the kinds of promising results we believe can be achieved when the industry and regulators work together to improve shellfish safety.

Thank you for your consideration of our comments in the process of developing performance standards for *Vibrio vulnificus* and *Vibrio parahaemolyticus*. We look forward to working with the Food and Drug Administration to develop policies which promote the complementary goals of enhanced seafood safety and a growing shellfish industry.

Sincerely,



Ron Wyden
U.S. Senate



Gordon H. Smith
U.S. Senate

cc: Dockets Management Branch [Docket No. 98P-0504]

Dr. Patricia S. Schwartz

Original letter to for copy rec'd
No. 99-2715

The Honorable

Dear Senator Wyden:

Thank you for your letter of April 15, 1999, also signed by Senator Gordon Smith, on behalf of the West Coast shellfish industry, concerning the petition for a performance standard for *Vibrio vulnificus* in shellfish filed with the Food and Drug Administration (FDA) by the Center for Science in the Public Interest. FDA published a request for comments on this petition in the *Federal Register* of January 21, 1999.

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Thank you for your thoughtful comments. We have entered them into the Administrative Record for this petition and they will be considered in the Agency's deliberations on this petition.

Please contact us if we may be of further assistance in this matter. A similar letter has been sent to Senator Smith.

Sincerely,

Melinda Plaisier
Interim Associate Commissioner for Legislative Affairs

Cc: HFA-305 (Docket No 98P-0504)

Bcc: HFW-10 (2)
HFW-2
HFW-12

R/d:eck; 4/27/99

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